

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Julian Edward Sale et al.  
Serial Number: 10/733,532  
Filing Date: December 11, 2003  
Title: Method for generating diversity

Group Art Unit: 1636  
Examiner: Daniel M. Sullivan  
**CONFIRMATION NO: 9057**

Certificate of Electronic Filing

I hereby certify that the attached Information Disclosure Statement and all marked attachments are being deposited by Electronic Filing on August 31, 2007 by using the EFS - Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Ann Lygas

Ann Lygas

Date: August 31, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

Applicant hereby submits an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant respectfully requests that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant further requests that the Examiner initial and return the attached forms PTO/SB/08 in accordance with MPEP §609.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - ☐ (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☒ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
  - ☒ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ 37 CFR §1.97(e). Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(c)(1) as provided for under MPEP 609.04(b) V.
- E. ☐ Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: \_\_\_\_\_

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.33547-731.302).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

8/29/07

By: \_\_\_\_\_

Jeffrey W. Guise  
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/733,532	
			Filing Date	December 11, 2003	
			First Named Inventor	Julian Edward SALE	
			Art Unit	1636	
			Examiner Name	Daniel M. Sullivan	
Sheet	1	Of	4	Attorney Docket Number	33547-731.302

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	1.	ANDERSSON, K. et al., "Affinity selection and repertoire shift: paradoxes as a consequence of somatic mutation?" Immunological Reviews 162:173-182 (1998)	
	2.	AZUMA, T., "Somatic hypermutation in mouse $\lambda$ chains," Immunological Reviews 162:97-105 (1998)	
	3.	BLANDEN, R. et al., "The signature of somatic hypermutation appears to be written into the germline IgV segment repertoire," Immunological Reviews 162:117-132 (1998)	
	4.	DIAZ, M. and FICJNIK, M., "Evolution of somatic hypermutation and gene conversion in adaptive immunity," Immunological Reviews 162:13-24 (1998)	
	5.	DORNER, T. et al., "Analysis of the targeting of the hypermutational chemistry and their impact of subsequent selection on the distribution of nucleotide changes in human $V_HDJH$ rearrangements," Immunological Reviews 162:161-171 (1998)	
	6.	GREEN, N. et al., "Immunoglobulin hypermutation in cultured cells," Immunological Reviews 162:77-87 (1998)	
	7.	HSU, E., "Mutation, selection, and memory in B lymphocytes of exothermic vertebrates," Immunological Reviews 162:25-36 (1998)	

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	8.	KLEIN, U. et al., "Somatic hypermutation in normal and transformed human B cells," Immunological Reviews 162:261-280 (1998)	
	9.	KNIGHT, K. and BARRINGTON, R., "Somatic diversification of IgH genes in rabbit," Immunological Reviews 162:37-47 (1998)	
	10.	KONG, Q. et al., "Recombination-based mechanisms for somatic hypermutation," Immunological Reviews 162:67-76 (1998)	
	11.	KOSMAS, C. et al., "Somatic hypermutation of immunoglobulin variable region genes: focus on follicular lymphoma and multiple myeloma," Immunological Reviews 162:281-292 (1998)	
	12.	LOPEZ, O. et al., "A single V <sub>H</sub> family and long CDR3s are the targets for hypermutation in bovine immunoglobulin heavy chains," Immunological Reviews 162:55-66 (1998)	
	13.	MAGE, R., "Diversification of rabbit V <sub>H</sub> genes by gene-conversion-like and hypermutation mechanisms," Immunological Reviews 162:49-54 (1998)	
	14.	MANSER, T. et al., "The roles of antibody variable region hypermutation and selection in the development of the memory B-cell compartment," Immunological Reviews 162:183-196 (1998)	

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	15.	McINTOSH, R. et al., "Somatic hypermutation in autoimmune thyroid disease," Immunological Reviews 162:219-231 (1998)	
	16.	NEUBERGER, M. et al., "Monitoring and interpreting the intrinsic features of somatic hypermutation," Immunological Reviews 162:107-116 (1998)	
	17.	NG, V. and McGRATH, M., "The immunology of AIDS-associated lymphomas," Immunological Reviews 162:293-298 (1998)	
	18.	SONG, H. et al., "Antibody feedback and somatic mutation in B cells: regulation of mutation by immune complexes with IgG antibody," Immunological Reviews 162:211-218 (1998)	
	19.	STEVENSON, F. et al., "Insight into the origin and clonal history of B-cell tumors as revealed by analysis of immunoglobulin variable region genes," Immunological Reviews 162:247-259 (1998)	
	20.	STORB, U., "Progress in understanding the mechanism and consequences of somatic hypermutation," Immunological Reviews 162:5-11 (1998)	
	21.	SLORB et al., "Cis-acting sequences that affect somatic hypermutation of Ig genes," Immunological Reviews 162:153-160 (1998)	

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	22.	WIENS, G. et al., "Harmful somatic mutations: lessons from the dark side," Immunological Reviews 162:197-209 (1998)	
	23.	WILSON, P. et al., "Amino acid insertions and deletions contribute to diversify the human Ig repertoire," Immunological Reviews 162:143-151 (1998)	
	24.	WINTER, D. and GEARHART, P., "Dual enigma of somatic hypermutation of immunoglobulin variable genes: targeting and mechanism," Immunological Reviews 162:89-96 (1998)	
	25.	WYSOCKI, L. et al., "Somatic origin of T-cell epitopes within antibody variable regions: significance to monoclonal therapy and genesis of systemic autoimmune disease," Immunological Reviews 162:233-246 (1998)	
	26.	ZHENG, B. et al., "Immunoglobulin gene hypermutation in germinal centers is independent of the RAG-1 V(D)J recombinase," Immunological Reviews 162:133-141 (1998)	

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